REMARKS

Claims 7-11, 13-15, 35-36, 40-42, 59-71, 73-77, 80-84, 86-94, 96-97 are currently in the present application. Claims 42, 71 and 96, and 98 are presently amended. Claims 1-6, 12, 16-34, 37-39, 43-58, 72, 78, 79, 95, 97, and 98 are cancelled.

Applicants contend that the amendments are fully supported by the application as filed, and that no new matter has been or was intended to be added to the claims by virtue of these amendments. Entry of the amendments and favorable consideration of the claims is requested.

Rejections under 35 USC §112

Claims 4, 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-94, and 96 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement and/or 35 USC §112, second paragraph, as being indefinite. Claims 4, 78, 79, and 85 are now cancelled, rendering the reje ction as applied these claims moot. With respect to Claim 96, the term "biologically acceptable hydrophilic polymer" (which formed the basis for the rejection under §112) is removed, rendering the rejection moot.

With respect to the remaining claims 7-9, 11, 13-15, 35-36, 40-42, 59-60, 71-77, 80-94, and 96, the Office asserts that the term "rapidly and completely dissolve on moist surfaces" (Claims 71, and 96, and claims dependent thereon)is a relative term that renders the claim indefinite. Applicants have amended claims 71 and 96 to remove the language "rapidly and completely dissolve on moist surfaces" to clarify that the recited tablets are "capable of rapid dissolution suitable for buccal delivery." Applicants contend that one of ordinary skill in the art would be apprised of the scope of the invention as required by 35 USC §112, second paragraph with respect to this feature. In support, the Office is referred to the Declaration of Michael Triplett, Ph.D., (of record dated 11/23/2010) wherein it is stated that: "[t]he term 'rapid release' (rapid dissolve) or 'immediate release' refers to a drug product which has zero-order or first order release of the active agent from the product and which releases the active agent in seconds or minutes rather than hours." Applicants further contend that the term "buccal delivery" is a term readily understood by one of skill in the art (meaning "the delivery of a medication by

application to the buccal mucosa"), and would readily apprise one of ordinary skill in the art as to the metes and bounds of the claim scope.

Applicants contend that, in view of the clarifying amendment now made, the rejection to claims 71 and 96, and claims dependent thereon, is now moot. Withdrawal of the rejection on this basis is requested.

Rejections under 35 USC §103

Claims 4, 7-9, 11, 13-16, 35, 36, 40-42, 59, 60, 71-94, and 96-97 stand rejected under 35 USC §103 over Coffee (WO-98/03267) in view of Liu et al (US 6,465,009) and Murray et al (US 6,709,669).

Applicants respectfully traverse all rejections to the extent the rejections still apply to the claims as now amended. Under MPEP §2142, the Office bears the burden of factually supporting any *prima facie* case of obviousness. In sustaining a rejection under 35 USC §103, the asserted combination must teach or suggest *each and every* feature of a claim. *See, e.g. In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); *In re Wada and Murphy*, Appeal 2007-3733, *citing In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995); *In re Wada and Murphy, citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). Absent a teaching or suggestion, an obviousness rejection under 35 USC §103 cannot be maintained. In establishing a *prima facie* case, the Office must set forth "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." MPEP §2141 citing *KSR Int'l v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, *but whether the claimed invention as a whole* would have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983). References relied upon to support a rejection under 35 USC §103 must provide enabling disclosure, i.e., they must place the claimed invention in the possession of the public. *In re Payne*, 606 F.2d 303 (C.C.P.A. 1979). Furthermore, according to MPEP §2141.02, the prior art must be considered in its entirety, *including disclosures that teach away* from an applicant's claims. As the Examiner is well aware, "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis

of the facts gleaned from the prior art." MPEP §2142. If the Examiner does not prove a *prima facie* case of unpatentability, then without more, the Applicant is entitled to the grant of the patent. *See, e.g., In re Oetiker*, 977 F.2d 1443.

For at least the reasons set forth below, Applicant respectfully submits that the combined art of record fails to render any of the present claims obvious.

With respect to the rejection under 35 USC §103, Applicant submits that the art of record fails to teach or suggest all of the limitations recited in each independent claim in accordance with MPEP §2143.03. As an initial matter, Applicants wish to address the Examiner's assertion that the feature of a dissolvable tablet is a statement of intended use and is not afforded patentable weight. Applicants contend that this feature is limiting and should be considered. Applicants direct the Examiner's attention to MPEP §2111.02 concerning intended use recitations in the preamble of a claim. Applicants contend that, while not limited to the preamble, the direction of the MPEP in this respect applies. According to MPEP §2111.02, a statement of intended use "must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." Applicants contend that the feature of a rapidly dissolvable tablet suitable for buccal delivery results in a manipulative difference between the claimed invention and the cited art, as the cited art does not teach or suggest steps by which one could arrive at the rapidly dissolvable tablets as now claimed. Applicants therefore contend that this feature should be accorded patentable weight and considered in view of the references cited.

Coffee et al. disclose electrohydrodynamic methods, but fails to teach, *inter alia*, methods that would provide rapid dissolving tablet suitable for buccal delivery as now claimed. Liu is relied upon for teaching "formulation and method of manufacture of tablets comprising pharmaceutically active ingredient[s]." Office Action at p. 8. Barabas is relied upon as teaching "a process for the production of ibuprofen complexes with the vinylpyrrolidone copolymer..." Office action at p. 9. Murray is relied upon for teaching "a process for preparing fast-diintegrating dosage form [sic] comprising a carrier and an active ingredient (e.g. drug) wherein

the carrier is fish gelatin and fast-dispersing dosage form releases the active ingredient rapidly on contact with a fluid." Office Action at p. 9.

Applicants contend that none of these references satisfy the deficiencies of Coffee et al, in at least the respect that none of the cited references teach, suggest, or disclose a method of manufacturing a biodissolvable rapid dissolving tablet suitable for buccal delivery comprising, *inter alia*, the steps of supplying a biologically acceptable carrier liquid comprising a solution of a biologically acceptable polymer in a mixture of water and ethanol, wherein said water and ethanol are present in said carrier liquid at a ratio of from about 1:0.8 to about 1:1.5 using the process of electrohydrodynamic comminution (Claim 71) or supplying a biologically acceptable carrier liquid consisting essentially of 5 grams of fish gelatin in a solvent consisting of from about 7 ml to about 9 ml of water and from about 10 ml to about 11 ml of ethanol comprising one or more active ingredients dissolved or suspended therein and a flavoring agent using the process of electrohydrodynamic comminution (Claim 96). Accordingly, Applicants submit that the combined art of record fails to teach or suggest all of the limitations of amended independent claim 96 or claim 71 in accordance with MPEP §2143.03. Applicants therefore respectfully submit that the combined art of record fails to render the invention as now claimed obvious in accordance with MPEP §2143, and request withdrawal of the rejection for at least these reasons.

The above notwithstanding, Applicants contend the cited documents cannot be combined to sustain a *prima facie* case of obviousness. First, Applicants contend that modification of the products obtained in Coffee in the manner now claimed would render those products unsuitable for their intended purpose, as addressed in more detail below. Second, while the Office asserts that claim features reciting specific amounts of specific ingredients are considered to be attainable by routine experimentation and are not considered to be critical, viewing the documents cited in their entirety, Applicants contend that the cited documents actually teach away from the specific ingredients of the claimed invention, such that it would not be obvious to use these components at all, much less routinely optimize their use.

With respect to Coffee et al., taking the reference as a whole, Applicants contend modifying the reference in the manner now claimed would render the subject matter of Coffee

inoperable for its intended purpose, thus negating an assertion of obviousness. Coffee et al teach the manufacture of webs/mats for covering surfaces such as wounds (p.17-18)—Applicants contend that it would not be desirable for such coverings to be rapidly dissolvable, and that to make such coverings rapidly dissolvable would render the coverings of Coffee unsuitable for the intended purpose. Coffee et al further teach that the resulting material, when in the form of fibrils, may actually "stick to the surface, for example, skin or soft tissue..." (p. 23.) Applicants contend that this feature would not be desirable in the manufacture of rapidly dissolving tablets suitable for buccal delivery as presently claimed. Finally, Coffee et al disclose methods for the manufacture of microcapsules for inhalation (p.29) that may be suspended in a liquid (p.25). Applicants contend that the methods of the instant invention, resulting in a rapidly dissolvable tablet, would not be compatible with liquid suspensions taught by Coffee et al. Accordingly, Applicants contend that Coffee et al. teach away from the claimed invention in at least the aforementioned aspects, and as such, cannot properly support a conclusion of obviousness. Accordingly withdrawal of the rejection on this basis is respectfully requested.

With respect to the recited ingredients and the recited process as a whole, Applicants contend that Liu et al. and Murray et al. are similarly problematic. Applicants contend that neither Liu nor Murray contemplates electrohydrodynamic comminution based methods, and both references teach away from various aspects of the instant invention. For example, Applicants contend that Liu et al. teaches away from the specific ingredients now claimed, teaching that "many tablet manufacturing processes use organic solvents, thereby leaving unwanted and undesirable organic solvent residues in the final tablet formulation" and "*it would further be advantageous if such tablets could be made ... without the use of organic solvents.*" Emphasis added. In contrast, both independent claims 71 and 96 require the presence of ethanol in forming the rapidly dissolving tablets using electrohydrodynamic comminution. Likewise, the Examples of Murray (*See, e.g.*, Examples 1-4) suggest that water is the only suitable solvent for preparing the disclosed dosage forms, and, as is the case with all of the secondary references, does not teach, suggest, or otherwise motivate one of skill in the art to combine the process of Coffee et al. with the manufacture of rapidly dissolving tablets. Thus, the cited documents do not lead one to combine the manufacture of rapidly dissolving tablets with the processes of Coffee et al, particularly where ethanol is required.

Accordingly, for at least the foregoing reasons, Applicants contend that the relied upon references cannot properly be combined to support a *prima facie* case of obviousness. Withdrawal of the rejection under 35 USC §103 and reconsideration and allowance of the claims is respectfully requested.

CONCLUSION

While several distinctions have been noted over the art of record, Applicant notes that there may be other limitations recited in the present claims which are neither taught nor suggested by the art of record. Applicant expressly reserves all rights and arguments with respect to distinctions not explicitly noted herein. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments.

With regard to all claims not specifically mentioned, these are believed to be allowable not only in view of their dependency on their respective base claims and any intervening claims, but also for the totality of features recited therein. The absence of additional patentability arguments should not be construed as either a disclaimer of such arguments or that such arguments are not believed to be meritorious. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should not be construed as an acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate or proper.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance. Should the Examiner wish to discuss the amendments or arguments made herein, Applicant invites the Examiner to contact the undersigned at (513) 369-4811 or via e-mail at ntepe@fbtlaw.com.

Respectfully submitted,

RONALD COFFEE et al.

By _____

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